

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, <i>ex rel.</i>	:	
DILBAGH SINGH, M.D., PAUL KIRSCH, M.D.,	:	
V. RAO NADELLA, M.D., and	:	Civil Action No. 04-186E
MARTIN JACOBS, M.D.,	:	
	:	
Relators,	:	
	:	
v.	:	
	:	
BRADFORD REGIONAL MEDICAL CENTER,	:	
V & S MEDICAL ASSOCIATES, LLC,	:	
PETER VACCARO, M.D.,	:	
KAMRAN SALEH, M.D.,	:	
and DOES I through XX,	:	
	:	
Defendants.	:	

ANSWER

Defendants V&S Medical Associates, LLC ("V&S Medical"), Peter Vaccaro, M.D. ("Vaccaro"), and Kamran Saleh, M.D. ("Saleh") (collectively, the "V&S Defendants"), through their undersigned attorneys, answer the Complaint as follows:

1. The allegations contained in Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
2. The allegations contained in Paragraph 2 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
3. The allegations contained in Paragraph 3 are directed to Bradford Regional Medical Center ("BRMC"), and, therefore, no response is required from these defendants. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity

of the allegations in Paragraph 3. Strict proof of the same is demanded. In further response, the allegations contained in Paragraph 3 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

4. The allegations contained in the second sentence of Paragraph 4 are directed to BRMC, and, therefore, no response is required from these defendants. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the second sentence of Paragraph 4. Strict proof of the same is demanded. The remaining allegations contained in Paragraph 4 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

5. The allegations contained in Paragraph 5 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

6. The allegations contained in Paragraph 6 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

7. The allegations contained in Paragraph 7 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the False Claims Act, 31 U.S.C. § 3729, et seq. ("the Act"), speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Act.

8. The allegations contained in Paragraph 8 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, Section 3732 of the Act speaks for itself and these defendants deny plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Act.

9. The allegations contained in Paragraph 9 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Act speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Act.

10. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 10. Strict proof of the same is demanded.

11. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 11. Strict proof of the same is demanded.

12. The allegations contained in Paragraph 12 are admitted.

13. The allegations contained in Paragraph 13 are admitted.

14. The allegations contained in Paragraph 14 are admitted.

15. It is denied that Saleh is an individual residing in McKean County. The remaining allegations contained in Paragraph 15 are admitted.

16. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 16. Strict proof of the same is demanded.

17. It is denied that the V&S Defendants engaged in any fraudulent practices. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 17. Strict proof of the same is demanded.

18. The allegations contained in Paragraph 18 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Act speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Act.

19. The allegations contained in Paragraph 19 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Anti-kickback Statute, 42 U.S.C. § 1320-7b(b), speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Anti-kickback Statute.

20. The allegations contained in Paragraph 20 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Anti-kickback Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Anti-kickback Statute.

21. The allegations contained in Paragraph 21 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute, 42 U.S.C. § 1395nn, speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

22. The allegations contained in Paragraph 22 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute and the relevant sections of the Omnibus Budget Reconciliation Act of

1989, P.L. 101-239, § 6204, speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute and/or the Omnibus Reconciliation Act.

23. The allegations contained in Paragraph 23 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute and the relevant sections of the Omnibus Budget Reconciliation Act of 1989, P.L. 103-66, § 13562, and the Social Security Act Amendments of 1994, P.L. 103-432, § 152, speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute, the Omnibus Reconciliation Act, and/or the Social Security Act Amendments of 1994.

24. The allegations contained in Paragraph 24 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

25. The allegations contained in Paragraph 25 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

26. The allegations contained in Paragraph 26 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

27. The allegations contained in Paragraph 27 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

28. The allegations contained in Paragraph 28 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

29. The allegations contained in Paragraph 29 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

30. The allegations contained in Paragraph 30 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

31. The allegations contained in Paragraph 31 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the Stark Statute speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Stark Statute.

32. The allegations contained in Paragraph 32 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further

response, the relevant sections of Title XVIII of the Social Security Act, known as the Medicare Program, speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

33. The allegations contained in Paragraph 33 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the relevant sections of the Medicare Program speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

34. The allegations contained in Paragraph 34 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the relevant sections of the Medicare Program speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

35. The allegations contained in Paragraph 35 are directed to BRMC, and, therefore, no response is required from these defendants. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 35. Strict proof of the same is demanded.

36. The relevant sections of the Medicare Program speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

37. The relevant sections of the Medicare Program and related regulations speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

38. The relevant sections of the Medicare Program and related regulations speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

39. The allegations contained in Paragraph 39 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the relevant sections of the Medicare Program and related regulations speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

40. The allegations contained in Paragraph 40 are directed to BRMC, and, therefore, no response is required from these defendants. Furthermore, the V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 35. Strict proof of the same is demanded.

41. The relevant sections of the Medicare Program and related regulations speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

42. The allegations contained in Paragraph 42 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further response, the relevant sections of the Medicare Program and related regulations speak for themselves

and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

43. The allegations contained in Paragraph 43 are denied.

44. The allegations contained in Paragraph 44 are denied.

45. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 45. Strict proof of the same is demanded.

46. The allegations contained in Paragraph 46 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

47. The allegations contained in Paragraph 47 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

48. The allegations contained in Paragraph 48 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. The relevant sections of the Medicare Program speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the Medicare Program.

49. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 49. Strict proof of the same is demanded. In further response, the allegations contained in Paragraph 49 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

50. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 50. Strict proof of the same is

demanded. In further response, the allegations contained in Paragraph 50 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

51. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 51. Strict proof of the same is demanded. In further response, the allegations contained in Paragraph 51 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

52. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 52. Strict proof of the same is demanded. In further response, the allegations contained in Paragraph 52 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

53. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 53. Strict proof of the same is demanded.

54. The allegations contained in Paragraph 54 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

55. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 55. Strict proof of the same is demanded.

56. The allegations contained in Paragraph 56 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

57. The allegations contained in Paragraph 57 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied. In further

response, the federal Medicaid statute speak for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the federal Medicaid statute.

58. The allegations contained in Paragraph 58 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

59. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 59. Strict proof of the same is demanded.

60. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 60. Strict proof of the same is demanded.

61. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 61. Strict proof of the same is demanded.

62. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 62. Strict proof of the same is demanded.

63. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 63. Strict proof of the same is demanded.

64. The allegations contained in Paragraph 64 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

65. The allegations contained in Paragraph 65 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

66. It is admitted that the V&S Defendants sought reimbursement from state Medicaid programs. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 66. Strict proof of the same is demanded.

67. It is admitted that the V&S Defendants are enrolled in and sought reimbursement from TRICARE/CHAMPUS. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 67. Strict proof of the same is demanded.

68. The relevant statutes and regulations for the TRICARE/CHAMPUS speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the TRICARE/CHAMPUS Program.

69. The relevant statutes and regulations for the TRICARE/CHAMPUS speak for themselves and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the TRICARE/CHAMPUS Program.

70. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 70. Strict proof of the same is demanded.

71. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 71. Strict proof of the same is

demanded. In further response, the allegations contained in Paragraph 71 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

72. V&S is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 72. Strict proof of the same is demanded.

73. It is admitted that the V&S Defendants submitted requests for reimbursement from TRICARE/CHAMPUS. Except as so admitted, the remaining allegations in Paragraph 73 are denied.

74. The allegations contained in Paragraph 74 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

75. The allegations contained in Paragraph 75 are denied.

76. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 76. Strict proof of the same is demanded.

77. The allegations contained in Paragraph 77 are denied.

78. The allegations contained in Paragraph 78 are denied.

79. The allegations contained in Paragraph 79 are denied.

80. It is admitted that BRMC agreed to sublease nuclear cardiology equipment from V&S, and the terms of the sublease agreement speak for themselves. Except as so admitted, the remaining allegations in Paragraph 80 are denied.

81. The allegations contained in Paragraph 81 are denied. It is further averred that V&S Medical's lease with GE Healthcare Financial speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the lease.

82. The allegations contained in Paragraph 82 are denied. It is further averred that said sublease agreement speaks for itself and these defendants deny Plaintiffs' allegations to the extent that they inaccurately or incompletely characterize the terms of the sublease agreement.

83. The allegations contained in Paragraph 83 are denied.

84. The allegations contained in Paragraph 84 are denied.

85. The allegations contained in Paragraph 85 are denied.

86. The allegations contained in Paragraph 86 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

87. The allegations contained in Paragraph 87 are denied.

88. The allegations contained in Paragraph 88 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

89. The allegations contained in Paragraph 89 are admitted.

90. The allegations contained in Paragraph 90 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

91. The allegations contained in Paragraph 91 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

92. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 92. Strict proof of the same is demanded.

93. The V&S Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.

First Cause of Action
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

94. Paragraph 94 is an incorporation paragraph to which no response is required. The V&S Defendants repeat and incorporate the responses contained in Paragraphs 1 through 93 above as if fully set forth herein.

95. The allegations contained in Paragraph 95 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

96. The allegations contained in Paragraph 96 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

Second Cause of Action
(False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(2))

97. Paragraph 97 is an incorporation paragraph to which no response is required. The V&S Defendants repeat and incorporate the responses contained in Paragraphs 1 through 96 above as if fully set forth herein.

98. The allegations contained in Paragraph 98 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

99. The allegations contained in Paragraph 99 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

Third Cause of Action
(False Claims Act: Making or Using False
Record or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(7))

100. Paragraph 100 is an incorporation paragraph to which no response is required. The

V&S Defendants repeat and incorporate the responses contained in Paragraphs 1 through 99 above as if fully set forth herein.

101. The allegations contained in Paragraph 101 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

102. The allegations contained in Paragraph 102 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

**Fourth Cause of Action
(False Claims Act: Conspiring to Submit False Claims)
(31 U.S.C. § 3729(a)(3))**

103. Paragraph 103 is an incorporation paragraph to which no response is required. The V&S Defendants repeat and incorporate the responses contained in Paragraphs 1 through 102 above as if fully set forth herein.

104. The allegations contained in Paragraph 104 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

105. The allegations contained in Paragraph 105 are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

The V&S Defendants deny that Plaintiffs/Relators are entitled to any of the relief sought in their Prayer For Relief, including subparagraphs 1 through 6, and request that judgment be entered in their favor and against Plaintiffs/Relators with prejudice, together with costs, attorneys' fees, and any other relief that justice requires.

AFFIRMATIVE AND ADDITIONAL DEFENSES

106. The V&S Defendants incorporate paragraphs 1 through 105 of their Answer as if fully restated herein, and interpose the following Defenses to the claims asserted by the Plaintiffs:

First Defense
Failure to State a Claim

107. The Complaint fails to state a claim against Defendants for which relief can be granted.

Second Defense
Lack of Jurisdiction

108. This Court lacks subject matter jurisdiction over this matter.

Third Defense
Lack of Wrongful Conduct

109. The V&S Defendants did not present or cause to be presented any false claim, record or statement to the United States Government.

110. The V&S Defendants did not violate any provisions of Pennsylvania or Federal law.

111. The V&S Defendants did not breach any duties under the laws, rules or regulations of the Commonwealth of Pennsylvania or the Federal Government.

112. The V&S Defendants did not engage in any wrongful conduct, any knowing misrepresentations, or any fraud with respect to the Commonwealth of Pennsylvania or the United States of America.

Fourth Defense
Lack of Causation

113. The V&S Defendants did not submit or certify any hospital cost reports, and did not cause any hospital cost reports to be filed with the Government, let alone any hospital cost reports containing false statements.

**Fifth Defense
Good Faith**

114. The Defendants reasonably believed and continue to believe that any and all financial relationships that exist or may have existed between BRMC on the one hand and the V&S Defendants on the other comply with all applicable laws and regulations.

115. Therefore, any certification that BRMC may have made to the Government on its cost reports or otherwise relative to compliance with applicable rules and regulations was believed not to be false and did not violate the False Claims Act.

116. To the extent that any of the actions alleged by the Relators to have been taken by the V&S Defendants occurred, said actions were taken in good faith and not with any improper or illegal purpose or intent.

**Sixth Defense
Lack of Standing**

117. The United States Government has declined to intervene in this action.

118. None of the Relators have alleged to have suffered or have suffered any harm or injury as a result of any of the actions alleged to have been taken by the Defendants.

119. Insofar as Relators have not suffered harm as a result of Defendants' alleged actions and the Government has declined to intervene, Relators lack standing to bring this Action.

**Seventh Defense
Compliance with Anti-kickback Safe Harbors**

120. Any and all financial relationships that may have existed between BRMC on the one hand and the V&S Defendants on the other comply with applicable safe harbor regulations promulgated under the Medicare Anti-kickback statute at 42 C.F.R. § 1001. Therefore, any

certification that BRMC may have made to the Government on its cost reports or otherwise relative to compliance with applicable rules and regulations was not false and did not violate the False Claims Act.

**Eighth Defense
Compliance with the Stark Law**

121. The equipment sublease at issue in this case does not give rise to either a direct or an indirect financial relationship within the meaning of the Physician Self-Referral Statute (“the Stark Law”) 42 U.S.C. § 1395nn, and the regulations thereunder at 42 C.F.R. §§ 411.350 to 411.361, and therefore, the Stark Law does not apply to it. There is no direct financial relationship, because the sublease is between a hospital and a limited liability company, not between a hospital and an individual physician or physicians. There is not an indirect financial relationship, because the aggregate compensation ultimately received by the physicians does not vary with, or otherwise reflect, the volume or value of referrals or other business generated by the physicians for the hospital.

122. In the alternative, any and all financial relationships that may have existed between BRMC on the one hand and the V&S Defendants on the other comply with applicable exceptions set forth in the Stark Law, 42 U.S.C. § 1395nn, and the regulations thereunder at 42 C.F.R. §§ 411.350 to 411.361. Therefore, any certification that BRMC may have made to the Government on its cost reports or otherwise relative to compliance with applicable rules and regulations was not false and did not violate the False Claims Act.

**Ninth Defense
Certification of Compliance Not a Condition of Payment**

123. The certifications of compliance contained in the Medicare cost reports referred to in Relators’ Complaint are not required as a condition of payment by Medicare, Medicaid or

CHAMPUS. Therefore, even if said certifications were incorrect or false, that fact would not give rise to an action under the False Claims Act.

Tenth Defense
Complaint Based on Cost Reports That Were Not Filed

124. The Medicare, Medicaid and CHAMPUS cost reports covering the cost reporting periods when the lease between BRMC and V&S Medical Associates was in effect were not filed and could not have been filed until long after the date that the Complaint was filed. Therefore, no certifications of compliance with applicable laws and regulations that may have been contained in those cost reports were made at the time the Complaint was filed.

Eleventh Defense
Unconstitutionality of False Claims Act

125. To the extent that penalties under the False Claims Act grossly exceed any actual damage incurred by the Government as a result of any claims paid, said Act violates the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, and therefore is void.

WHEREFORE, the V&S Defendants pray this Honorable Court to dismiss all claims against them, with prejudice, and to award the V&S Defendants all costs and such other relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Defendants V&S Medical Associates, LLC, Peter Vaccaro, M.D. and Kamran Saleh, M.D. hereby demand a trial by jury in this matter.

Respectfully submitted,

By: /s/ Carl J. Rychcik
Jay D. Marinstein, Esquire
PA I.D. No. 53163

Carl J. Rychcik, Esquire
PA I.D. No. 73754

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Counsel for Defendants,
V & S Medical Associates, LLC,
Peter Vaccaro, M.D. and Kamran Saleh, M.D.

Dated: October 13, 2006

CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached document was filed electronically with the United States District Court for the Western District of Pennsylvania and also served on each of the following attorneys in the manner set forth below on this 13th day of October, 2006:

via electronic transmission:

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